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BASIC AND TRANSLATIONAL RESEARCH

STRATEGIC PLAN QUESTION 4 PLANNING GROUP
CONFERENCE CALL

THURSDAY, SEPTEMBER 26, 2013

The Strategic Plan Question 4 Planning Group convened via conference call at 1:30 p.m., Susan Daniels, *Executive Secretary*, IACC presiding.

PARTICIPANTS:

SUSAN DANIELS, Ph.D., *Executive Secretary*, IACC,
Office of Autism Research Coordination (OARC),
(NIMH)

THOMAS INSEL, M.D., *Chair*, IACC, National
Institute of Mental Health (NIMH)

IDIL ABDULL, Somali American Autism Foundation

ANSHU BATRA, M.D., Our Special Kids

TIFFANY FARCHIONE, M.D., U.S. Food and Drug
Administration (FDA)

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PROCEEDINGS:

Operator: Welcome, and thank you for standing by. At this time, all participants will be in a listen-only mode. Today's conference is being recorded. If you have any objections, you may disconnect at this time.

I would now like to introduce your host, Dr. Susan Daniels. You may begin.

Dr. Susan Daniels: Hello. Welcome to this call of the Question 4 Planning Group of the Interagency Autism Coordinating Committee. We welcome all our listening guests who are in the public and the members of this Planning Group.

We have four members in this Planning Group at the moment who are members of the IACC. We are waiting for Dr. Tom Insel, who should be arriving on the call shortly. But let me just go ahead and do a roll call.

Idil Abdull?

Ms. Idil Abdull: Here.

Dr. Daniels: Anshu Batra?

Dr. Anshu Batra: Here.

Dr. Daniels: Tiffany Farchione?

Dr. Tiffany Farchione: Here.

Dr. Daniels: Great. That was one of the shortest roll calls I've had to do lately.

[Laughter]

So it appears that all of us except Dr. Insel are on the call at this time. And as I said, Dr. Insel, hopefully, will be joining us in a few minutes, but we didn't want to keep everyone waiting for too long to begin the call.

So the purpose of this call today is to talk about Question 4 and the Strategic Plan update that we're going to be doing this fall, and this is the first of a series of calls that will be each covering a different question in the IACC Strategic Plan that has seven different question areas covering various areas of research and research-related activities.

This first set of calls that will be taking place over the next week or so will be looking at documents created by the portfolio analysis process that the OARC does on behalf of the IACC. And this process has happened over the past 5 years, and there are 5 years' worth of data now.

And the IACC has decided that it would like to do a look back over the past 5 years of funding to try to determine what the status is of each of the Strategic Plan objectives and the overall status of each question in the Strategic Plan as part of the planning process for updating the Strategic Plan.

Dr. Insel has just arrived with us and will be joining the call. So I sent out a number of materials to the group, and anyone who is listening to this call remotely, all of the materials are available on the IACC Web site. If you go to the Meetings and Events page and look for this meeting, there's a link to the materials, and you also will find the agenda for the meeting today.

And the agenda is basically going to cover a discussion of these materials to get through the questions that were put together by the Committee to help each planning group get a sense of the status of progress toward completing objectives in the Strategic Plan and completing some of the major goals of the Strategic Plan.

So first, I would like to -- I've got a list in the agenda of the different reference documents. We have the first one, which is the 5-year Strategic Plan Status Chart for Question 4 and also known as the cumulative funding chart. And this chart shows across the entire Strategic Plan what has happened in the past 5 years in terms of funding.

The electronic version has some live links that the Committee can use to look at the projects that underlie each of the 2008 through 2010 objectives in the Strategic Plan. For 2011 and 2012, we've prepared lists of the projects because the Web tool is not live for 2011 and 2012 yet because we are still working on the final Portfolio Analysis Report, and we'll be making all of the Web tool parts of that live at the time that we release the Portfolio Analysis Report.

So does anyone have any questions about this document? I assume that everyone had a chance to review it and read through the various caveats that OARC put in the front of this document to try to explain how this document can be read and some

of the limitations or some of the features of this document and how it can be used.

Each year has -- each objective goes through all 5 years, and we have some color indicators -- green, yellow, and red -- that are supposed to be just intuitive indicators to give you a sense of the general direction of funding in each of those areas. As a reminder, the Strategic Plan, when it was devised by the Committee, set forward objectives and came up with an estimated number of projects and an estimated -- or recommended -- budget for each objective, but these were considered to be a floor, not a ceiling, that these were the minimum -- these estimates described the minimum that would be required to achieve these objectives.

And so they were not a funding limit or a limitation on the number of projects that could be funded in these areas. And in fact, each of these objectives encompasses a broad or complex problem.

I think any of you could look at these objectives and agree that they cover areas that are very complex and may require multiple efforts

to achieve them.

So with that, I guess would somebody like to make any comments? Does anyone have any questions about the documents, about the information you see here?

Ms. Abdull: I have a question, Dr. Daniels. This is Idil.

Dr. Daniels: Sure.

Ms. Abdull: On the -- on the objectives, the ones that have red and that which means they were not funded, does that mean that -- that they were not funded because CAA was authorized but not fully funded so we ran out of money, or people just were not interested in funding those? Or how did that come about where some of those objectives in the red -- I really would like if they were funded and done. But I was just wondering how that -- how that process worked.

Dr. Daniels: Alright, so with the Federal funding that's been applied toward some of these objectives, the funding wasn't really applied toward the objectives. The funding is really a reflection of what each agency had in its funding

portfolio that applied to each of these objectives.

So the process is that OARC collects all of the projects from all of the agencies, as well as the private funders, and then works with the agency or private funder to code those projects to determine whether they happen to fall within some of these categories and then, from that, creates this pattern and is able to track which areas have received funding. But most agencies haven't necessarily directly targeted the objectives.

Although in some cases, they have, and sometimes they have put out targeted funding opportunity announcements to try to get investigators to come in with proposals that match the objectives.

But in most cases, the projects would be investigator initiated. So a researcher out in the community may have had this idea to do a project on this and asked for funding and, because of the merit of their proposal, was awarded funding by the agency.

In the case of the red, that indicates that no

agencies or organizations are currently funding or in whatever year the data were collected for were funding projects that correlated with this particular objective.

So in this, in Question 4, we have one objective, to convene a workshop to advance the understanding of clinical subtypes and treatment personalization -- what are the core symptoms to target for treatment studies -- by 2011. And so that workshop has not been funded by anyone.

Dr. Thomas Insel: This is Tom Insel. Sorry I'm late to the party here, but just catching up.

On that particular one, I thought there were a couple of meetings like that that were supported by Autism Speaks in 2011, another one from the Foundation for NIH supported in 2012. So we may want to go back and check on --

Dr. Daniels: The Foundation for NIH (FNIH) is not a funder that we have collected data from.

Dr. Insel: This may have been done collaboratively with both NIH and Autism Speaks.

Dr. Daniels: Okay.

Dr. Insel: I know I think it was through the

Biomarkers Consortium of FNIH that that was -- there was at least one autism-specific meeting, and I believe, actually, there's another one scheduled for Monday or Tuesday.

Dr. Daniels: Okay.

Dr. Insel: So maybe we can reach out more broadly and see. I'd be surprised if that actually -- that the specific wording here hadn't been entirely met, if not by 2011, by 2012.

Is there anybody on the phone from Autism Speaks? Either current Autism Speaks or previous, like Geri Dawson?

Dr. Daniels: Not -- not on this call today.

Dr. Insel: Okay. So Geri would know this. But they were -- I think they were the Santa Monica workshops

Dr. Daniels: Okay.

Dr. Insel: ...that were held in 2011, and one had to do specifically with identifying the core symptoms to target for treatment studies and identifying endpoints in assessments for that.

Dr. Daniels: Okay. We will check with Autism Speaks. We do collect data from them, but there

may have been some reason that we didn't get the data.

Dr. Insel: Well, it wouldn't -- it wouldn't show up in their grant portfolio because it's not -- it was something they did internally. It wouldn't come out of their -- their grant reports.

Dr. Daniels: Thank you for helping us with that. So then this may change. And all of the information, especially for 2011 and 2012, that information is still in draft because the portfolio analysis for 2011 and 2012 is not fully completed yet. So there may be updates. But 2008 through 2010 data is locked, and that's final data.

Dr. Batra: Susan, this is Anshu. First of all, I wanted to thank you again, you and your staff, for -- for collating all this data. It really helps to sort of see it in this manner.

And one comment, you know, looking at the objectives, objective number 2, standardize and validate at least 20 model systems.

Dr. Daniels: Mm-hmm.

Dr. Batra: It looks like clearly that one has

been funded the most robustly over the last 5 years. And -- and you know, looking specifically at that objective, to me, it seems like it's not really within the scope of this particular question in terms of treatments and interventions and specifically looking at the various projects that have been funded. To me, they seem very much more relevant to Question 2 or Question 3 and --

Dr. Daniels: So this is Susan. I can -- I can fill in a little bit of the history of that, so when we did this exercise in 2009, we did what we're doing now, and we split into small groups. And what happened is the Question 4 group was the group that came up with this idea.

And so it ended up in Question 4, although in a lot of ways, model systems are very broad and apply to many areas and probably are most relevant to Question 2. And so it was a historical reason that it ended up in Question 4.

Dr. Insel: I think part of it was that the other piece here was we were struggling at that time -- and we still are -- with trying to engage industry in R&D in this area because in 2009 or

2008, I don't think there were any large companies that had a development program for -- for autism. And in 2009 and '10, many of them actually moved out of neuroscience in a big way, even more so in 2011.

When they moved out, in almost every case what they said was, "We're getting out of this area because we don't know what the targets are. We wouldn't know what to develop as the next small molecule or the next generation of treatments because we don't know what to target."

And the concept here was to -- to fund a serious effort that would generate some potential targets for pharmaceutical development or potentially, as it says, for neural circuits, for devices or other kinds of interventions, accepting the idea that this was a brain disorder and to come up with either medicines or devices that could be used to target that.

[Pause]

Dr. Batra: I see.

Dr. Insel: So I think it's very much the core of treatment development. That's sort of the --

it's -- the basic science piece of that is to come up with the next set of targets.

Dr. Daniels: And since there isn't a similar objective in Question 2, many of the model system type projects did get coded to this particular category because there is nothing similar in Question 2. But they had to be projects that had some relationship to identifying specific molecular targets or neural circuits amenable to existing or new interventions.

Dr. Batra: Yeah, I guess my concern is I see that big chunk of money going toward that particular objective. And again, as a public stakeholder and as a parent, you know, I think, yeah, eventually, 20, 30 years, this will -- this will hopefully come to fruition. But you know, what about -- what about the interventions that, you know, that I'm currently sort of have available to me right now for my son and for other people's children and, you know, that really are relevant for present day?

And you know, as I look at the objectives specifically for the things that are really

relevant for the public, which is the objective number 3, you know, that's -- that's a very slim percentage compared to number 2.

So anyway, that's -- that was -- that was a very, very -- that struck me, I guess, you know, in terms of looking at the -- at the past 5 years and where the funding has been, as a parent.

Dr. Insel: So you're thinking about sort of the balance issue here? Is that the right balance?

Dr. Batra: Yes, absolutely. Absolutely, Tom. I mean, I look at it, and I think all these objectives are relevant to some degree. But specifically for me as a parent, and as I've been listening to more and more parents and really, you know, at the concerns the parents have, you know, I think that there's definitely a -- a -- you know, a lack of balance in what the public wants and what -- really where the funding has been focused.

[Pause]

Dr. Daniels: Does anyone have other questions about this table or other comments about what you see in the funding or what you've seen in those

project lists?

We did try to point out changes to the language over time in the red and blue texts. As you read the text of the objectives, you can see changes and revisions that were made over the years, which also influenced some of the coding over the years because, as new things were added into these objectives, the new projects would be coded to them.

If there aren't any other comments on that, we can look at the other -- other documents that we have here. So we do have a document that shows the distribution across the entire Strategic Plan. All of the funding, that's the pie charts here -- for some reason they don't seem to be in my packet, but I think that those of you who have Web access, of course --

Dr. Batra: So, Susan, this is Anshu. Is that -- is that the pie chart for 2012 or --

Dr. Daniels: So we provided them; I believe you have 2008 through 2012 in your packet. I think my packet somehow didn't have -- have all of that in there, but you have them all. And maybe you're

more interested in 2012 because that's the most recent, but we included all of the years so that you could kind of look at the differences in case that was of interest to you.

Does anyone have any particular comments about -- about these charts?

Dr. Insel: We wanted you to have the multiple years so part of the question in front of us is what's been the impact of the Strategic Plan, and can you see changes in the pattern of funding over the period that we've had the Plan? So with respect to that, 2008 serves as a baseline.

Dr. Daniels: Mm-hmm, yes. So --

Dr. Insel: It shows how things have changed since then.

Dr. Daniels: So if you look at the 2008, right? Here it is in my packet.

Dr. Batra: So, again, this is Anshu. Looking at from 2008 to '12, you know, the trend has been, you know, 2008-2009, it was -- well, 2008 was the highest funded for this particular treatment section, 24 percent. And since then, it's been sort of steadily dropped down to about 20 percent.

So again, this is a nice, you know, pictorial to see where the funding is going, you know?

Dr. Daniels: And something to keep in mind over the years, as the IACC has decided to be able to keep this process open to new funders being included in the process and so forth, the percentages, you know, we're not tracking all the exact same funders over time. We're trying to get a stabilized core of funders, but that has also impacted. So a 4-percent change is probably not too meaningful.

Dr. Insel: And you want to look at the absolute dollars as well as the percentages. But it's a good point. It's kind of apples and oranges to go -- to compare the years. And yet we still thought it was important for you to see the picture --

Dr. Daniels: Right.

Dr. Insel: -- so you can get a sense of where the trends are.

Dr. Daniels: Yeah, so when you look at absolute dollars that there's been an increase that's, I guess, \$53,000 in 2008 to \$68,000 in --

oh, sorry. That's 2010.

Dr. Batra: Yeah, 2010 and 2012.

Dr. Daniels: Sixty-three. So -- so it hasn't been a -- it's been an increase overall in absolute dollars.

Dr. Insel: Okay.

Dr. Daniels: Okay? So then moving on to the next --

Ms. Abdull: Hi, Dr. Daniels. This is Idil. I have a -- I'm just wondering if I can make a comment about -- it looks like there is an overall increase in most of these studies and the objectives, but I just wonder, particularly as someone who has a child with classic autism or nonverbal autism, there isn't that much research -- or that has been done that says how do we teach these children to communicate if the words are not coming?

And I think Portia and the folks from California all made their point that over 25 percent of children with autism are not verbal, but yet we're always concentrating on the verbal kids and how to teach them. And I just wonder if

there are ways to recommend a specific treatment for nonverbal children or children that have classic autism and for not so much just behavior therapy, but more like communication devices and which devices would make these children be able to communicate and make their needs and wants met.

Dr. Daniels: Those kinds of projects are in the portfolio, but we didn't have particular direction in asking for us to pull those out for you. That's something that if this Planning Group wants it, we could always pull that out.

Dr. Insel: Yeah. So the -- it's the next bullet you'll see is the full project listings. So there had been RFAs, at least I know at least one RFA specifically in the area that you just described. But you'll have to -- what we've done here, what OARC has done here is to work with the Plan as it now sits.

And of course, as a full Committee, we're not going to rewrite the Plan at this point or even amend the Plan. This is really -- this is the time to look at the accountability of how we've done. So, and I guess, Susan, you were about to say

this, but the next category of information will allow you to drill into each of the wedges within Question 4 to get a very detailed picture of exactly what each project would be that has made up this -- this portfolio. So that, you know, you can actually see what has been funded with respect to nonverbal children or adults.

Dr. Daniels: Right. So on the next -- the next document that we have here is the subcategory pie chart for Question 4, and we just included the ones from the past 3 years because the subcategory coding was only done since 2010. So that's something that OARC developed in response to questions that the IACC had about what's really in especially the "Other" category that is all of the projects that don't map to a particular Strategic Plan objective.

There were members of the Committee who wanted to really get more information about that, and so OARC devised a subcategory coding scheme to try to not only drill into the other projects, but all of the projects to give you a sense in maybe a different kind of breakdown than the Strategic

Plan objectives offer to let you know what really is going on in those in each of the questions.

And so communication interventions isn't a specific breakdown in the current subcategory scheme. But you can see, actually, technology-based interventions and supports is probably largely communication devices. So you can imagine that you would have to look through the -- the specific coding in the Web tool.

And you can pull out these subcategories individually if you're interested in doing that. You can click on the subcategory and see the specific projects that went there, but my guess is that a lot of the technology-based interventions and supports are related to communication. There are probably some of them that are also social training tools.

So does anyone have any comments about this breakout of what is really in this question in terms of the science areas?

Dr. Batra: Susan, this is Anshu again. This, again, is a wonderful pictorial that speaks very loudly to me as I see, again, a large percentage

of the funding is going toward model systems in behavior and significantly less in areas that, again, I think that most of the public is really interested in, which is the complementary, dietary, alternative component, and that's 1 percent. And that's been pretty consistent for the last few years, the 1 percent.

Occupational, physical, sensory-based is 3 percent. That went up slightly over the next couple of years. And as Idil mentioned, you know, the technology, I think, you know, again, for nonverbal individuals, there is very little intervention, and most of it is behavioral.

And again, I'm not able to click on those little pies and generate the individual projects as you mentioned. But I can imagine there's very little in terms of nonverbal in education. Again, as we're looking at this, I'm assuming we're going to eventually get to how we make this more equitable at some point? Is that right, Susan?

Dr. Insel: No. Actually, I think the task for us, as a subgroup, is to look how -- two

questions. First, how has the funding evolved with respect to the Strategic Plan? So the Strategic Plan laid out a whole series of some 78 objectives. How are we doing in terms of a progress report on that?

And the first part is in terms of funding, number of projects, number of dollars. And the second part is to say what have we really gotten out of that in terms of knowledge? So has there been with this investment or with the research that's been done, what have we learned? Can some of these things now be taken off of the Plan? Do some of these things need additional attention? But --

Dr. Batra: And that's going to be at the second call? Is that right, Tom?

Dr. Daniels: It'll be the sum of all of these, but I think this call is going to focus on the funding information and what you can learn from that. The next call will focus on information about how the field is progressing in terms of the actual research or other types of projects that are related to the Strategic Plan.

So here we're talking really just about the funding information, and that's all that you have in front of you. But then we'll get into more details of the actual work in the next call.

Dr. Batra: So the accountability component, what Tom was describing, the accountability and what have we gotten out of our investment and as a way to then determine what the next steps are. Is that correct?

Dr. Daniels: Right.

Dr. Insel: Yeah. Yeah exactly and of course, there's a sort of paradox in here that if we were really, really smart, we wouldn't have to spend very much money at all to get the answers that we need. And so it's not necessarily the case that those areas where we spend the most money we get the most information.

So it's -- there really are two quite different kinds of questions in front of us. But the one initially, which is really straightforward, if given what -- given the Plan that we have, and that's what we're going to be working within -- how have we done since 2008 with

respect to each of those objectives, and what have we invested?

And then the next question is what's been the return on that investment? And if, you know, there may be things that --

Dr. Batra: So how are we going to be -- I'm sorry, Tom. Go ahead.

Dr. Insel: Well, I was just going to say there may be things that especially for people who weren't involved in the original development of the Strategic Plan, you might think that's not the way you would have done it. But this is really -- you know, we're in the ninth inning here. This is -- this isn't the time to rewrite the Plan.

Dr. Daniels: So on the -- you have the summary of all the -- or the listing of all the projects as well. I don't know if you had more comments on this subcategory sheet, but the last item that we gave you is a funding summary sheet that just tries to in one place give you a sweep of the way the changes in funding have -- have occurred, although keeping in mind that there may be different funders who have joined the pool over

time or funders who have left.

But overall, you can see that there has been an increase in funding for this question over time and that the percent of total ASD funding has remained relatively similar -- hasn't been a dramatic change.

And we've given you a quick snapshot of the status of the objectives in 2012. The one that was listed as having no funding in projects, the workshop, we've just received information that there might be a workshop or two that actually meet this objective. And so our Office will look into that and see if we can find out the information that might be needed to update that.

Dr. Insel: Well, that would be a great example where there's no funding, and yet it could have been completed, which would be the ideal.

Dr. Daniels: Right, right -- because we are limited to collecting these project listings from agencies, and most agencies use their typical grant funding as their main project list. But sometimes projects get funded through other mechanisms. In fact, there are two other workshops

that got funded through a different mechanism at NIH that are also in other questions and so had to be gathered in a different way.

Ms. Abdull: Hi. This is Idil. So I agree with Anshu that like, on the ground, around 2008 is when my son was diagnosed with autism. So on the ground in real life, a lot of parents are saying, "Which interventions work?"

So, and at this point, I don't think any doctor can say, "This one works for sure, and here you go. Go get this." So it's a lot of trial and error.

And I think if we can do a lot of the stuff that parents are already doing, but there isn't research or we're not recommending enough research or it's not getting enough funding. Such a lot of the vitamins, a lot of the alternative treatments, a lot of nonverbal, you know, communication stuff. And because, Dr. Insel, you said how we are doing the last 5 years. And you know if I -- if I was giving a grade, I would say like a C- or even a D+.

When that question -- that's a good question,

which interventions are working? I think that should answer for any parent whose child is just now diagnosed. They shouldn't have to go through 20 million things and not know does research support this and spend thousands of dollars. I've spent thousands of dollars on my own on alternative treatments because I thought it would work, but there was no research behind it.

So not -- not that we want to change the Plan or in the ninth inning or any inning, but we want to make sure that what's happening in "Realville" on the ground is matching up with what we're recommending and also what's being done. And I get it that we're only a recommendation committee, and we can just recommend. But I think our recommendations a lot of times are taken.

So I just wonder if there is a way to balance it out in terms of the funding. For behavior, we know behavior, ABA, for smaller children works.

But even for behavior, we don't know for older kids. We don't know for RDI [relationship development intervention], Floortime, the other developmental [approaches], because autism is a

developmental disorder.

There isn't enough funding for those kinds of therapies, and I really would like if there is a way for us to recommend what parents are hungry for, which is please tell me which therapy works for my child so I'm not running around town all daylong trying to take him 20 million things because research says we're not sure which one works. If that makes sense?

Dr. Insel: Yeah, that does make sense. Let me just, again, share with you one other thought about this process that we're involved with here.

If you look at that table that Susan was just talking about, in 2012, there are 269 projects that are in process for Question 4, and we're talking about interventions. The average clinical trial from industry would be about 3 to 4 years, and from academia, it would be about 4 to 6 years.

So you know it may be that a lot of the questions you're asking are in process and would be worth really drilling into the list of projects that are currently being funded. The answers may not be there yet, but that doesn't mean that

nobody is paying attention to the question. It just means that people are working on it, and it does take years, not weeks or months, to do a careful, rigorous, properly powered clinical trial so that you can say with some confidence that a particular complementary treatment is useful or that it's not useful or that it's only useful for certain kinds of people.

So this is -- of all the questions that we're going to be looking at in the evaluation of the Plan and of the accounting exercise here, Question 4 is perhaps one of those in which it's got the longest tail to it. It's going to take a while for clinical -- for the assessment of -- interventions to really give you the answers either up or down on any of the interventions that are currently in play.

So what will be really important here is to actually go through the list of the 269 projects that were funded in 2012 to see what it is we're currently doing, even if we don't have them completed yet.

Dr. Daniels: The other thing that you can look

at is back on that first table, the cumulative funding table. In the total column, we've tried to give an indicator of where each of these objectives is in terms of the relationship to the IACC recommended budget, which was basically an estimate of how much it might cost to do the things that are recommended by the IACC.

It doesn't necessarily mean that it would take that much money. And in fact, if you could possibly do what is recommended with less money that would be efficient and desirable, I would think, for most, if you can achieve the goals without spending as much and be able to use any excess funds for other things.

But you may want to look down the list of objectives and get a sense of whether you think, based on the funding alone without necessarily knowing all of the outcomes of the research, whether in terms of funding each of these objectives is at a place where they're funded appropriately or if you think that they require additional attention.

Dr. Insel: Susan, I have a question. When you

go to that table you were talking about, the one that the title is IACC Strategic Plan Funding Summary Sheet, this is for Question 4, it looks like we peaked in 2010 --

Dr. Daniels: Mm-hmm.

Dr. Insel: -- both for Question 4 funding and for total ASD funding, and it's been down, a lot down, ever since. Is that because of Recovery Act dollars?

Dr. Daniels: Right. I think that a lot of it is probably due to the Recovery Act. We could verify that for you if you need that information.

[Pause]

Dr. Insel: Just looking at it, it appears that we were defunding the area after that. But if it's just Recovery Act, then it's -- that was money that had to be used in 2009-2010. So we knew that we were going to see a big decrease thereafter.

Dr. Daniels: As you look through the list of objectives, do you have a sense, based on the funding, of where you think these objectives are?

[Pause]

This particular question has quite a lot of

objectives.

Dr. Insel: So you were taking us back to the sheet that has the green, the yellow, and the red bars on it?

Dr. Daniels: Mm-hmm. That's probably the easiest one to work from.

Dr. Insel: This says Summary of the 2008 through 2012 Portfolio Analysis Data as Aligned for the IACC Strategic Plan.

Dr. Daniels: Right. Otherwise known as the cumulative funding table that's got the red, yellow, and green. There are 12 different objectives in this question. What is this group's sense of how these different objectives are faring in -- as of 2012?

Dr. Batra: Susan, this is Anshu again. I mean, you know, clearly, there has been funding for quite a few of the objectives that have been laid out over the last few years, and you know, again, what strikes me is the huge imbalance in -- in one particular area here. And in fact, you know, it went over budget by 50 percent and then, you know the clear disparity in the other regions.

Again, in an area that I -- you know, I think as parents are seeking questions and answers of sorts, very significant, you know, less funding and less than what was even recommended. So Question 3 recommended \$27.8 million, and only \$8.9 million was funded. Several other show the same -- similar pattern.

So again, you know, if you're asking for trends, I mean that's sort of what's evident here. Again, I'm curious, Tom, how -- how we -- I know we're here to make observations and -- and to make a summary of what's been happening the last 5 years. But then, you know, how do we -- how do we then change this to -- to again make it more relevant to what -- what really, you know, the public wants?

Dr. Insel: Well, the way I would understand this process, and again, it's up to the Committee about how you really want to go forward with what we do in 2013. But it seems to me the first step is to look at this analysis, get a sense of how you think we've done on each of the objectives.

Again, I would put it in terms of we're now

accounting for what the investment has been. I think you'd want to then bring in the experts, as well as have a deep discussion among ourselves about what's been the return on the investment. So in this case, you know, when you -- you were concerned about the model systems for finding new targets, the question would be how many targets have we gotten for \$100 million, and how are those being deployed? What's being done with them? So that would be a good question, I think, to try to understand.

And then the final piece of what we'll be involved with as a progress report this year is giving the full Committee and the public and ultimately the Congress some sense of how the IACC thinks we're doing on the Plan. So if you feel that there has not been enough attention in certain areas -- this is the "when" -- this is the opportunity to clarify that.

And I think to the extent that it can be framed as we have this spectacular opportunity to discover something or to prove or disprove something that is worthy of a new investment, that

would probably do better than to imply that we shouldn't be spending as much money as we are in certain areas.

Dr. Batra: Got it. Got it. I understand. That helps me. Thank you.

Dr. Insel: So, Susan, maybe it'd be helpful to sort of get a sense of, for today's meeting, what would you want from us as a group? What would be helpful at this point as we look at these objectives in the green and the yellow and the red?

And I would agree with Anshu. I think it's amazing to see it all laid out like this. It's kind of an incredible amount of work. What -- what do we need to do as a group that would move this whole process forward?

Should we kind of just reflect back that this looks okay and we need to have more information about the individual projects, or what -- what would be helpful?

Dr. Daniels: It would be helpful if you identified specific objectives that you think need more attention based on this. And you know, we

have highlighted for you the funding, but also take into account projects, because that's also an indicator of how much attention is being paid to these.

And if you could identify areas that you think really need additional attention -- it sounds like based on some of the comments that Idil and Anshu have made that there is a sense that more effort on the five widely used interventions, such as nutritional, medication, and assisted technologies and sensory integration-type interventions, that those types of studies should be prioritized more.

Currently, I guess, as of 2012, there were 17 projects identified that are addressing these kinds of things. But it sounds like there is an interest in trying to further intensify that particular area. But does the Committee or the Planning Group have any other areas that you feel are in great need of further attention or some need of further attention based on the information you have here?

Dr. Insel: How do we make sense of some of the numbers? Like, when you look at, what is it number

6 here, the "launch randomized controlled trials of interventions with bio-signatures and other measures to predict response." What the Plan called for, if I'm reading this right, is something like 11 trials with an estimated recommended budget of \$66 million.

There are now 21 projects, actually, maybe even more than that, depending on how -- I'm not sure how to read this. So it goes from 16 and 30, to 42, to 30, to 23, to 21.

Dr. Daniels: So this was a particularly confusing objective, and this is a result of sort of the history of how the Committee has worked because originally it was worded differently, and then a number of things were kind of compiled into one. And so -- but we're really tracking it as a whole. We're not tracking the individual pieces of it separately.

So that's kind of a compilation. So if you were to take a look through the 2012 listing of projects, which, I believe, is in your packets, you would see what types of trials and you could match them.

But we haven't -- OARC has not done a breakdown according to each of these separate sub-bullets.

Dr. Insel: Yeah, I don't think you should because I think that's really our job to understand what the individual projects look like.

But I'm just trying to understand this because by -- in terms of the number of projects, we've well exceeded. So the recommendation was for 11, and even the lowest number here would be 21 projects in 2012.

But in terms of the dollar amount, we're way under, right? So does that mean that one way for us to think about this is that there are many projects that are in this space, but they aren't powered appropriately or they're not scaled to give us what the Committee originally thought would be required or how best to interpret that?

And maybe this is a place where the individual grants will be assessed?

Dr. Daniels: Right. I think that you would have to look through that project list and see what's included there --

Dr. Insel: Okay.

Dr. Daniels: -- realizing --

Dr. Batra: Susan, this is Anshu. And specifically, Tom, just to add to your comments, we don't know how many of those projects are adults, are geared toward adults versus infants and toddlers, if they're all lumped together. Correct?

Dr. Insel: So --

Dr. Daniels: Right. Which is -- which is one of the, you know, limitations of lumping things together, and in the future, hopefully, the Committee will be able to maybe separate very distinct things into separate tracking categories so that it's easier to track them.

Dr. Insel: But some of them you can tell just from the title. So --

Dr. Daniels: Definitely. So --

Dr. Insel: -- some of them say, you know, RCT of cognitive enhancement for adults with ASD. So if we go to the table that you provided with all of the individual projects, this allows us to drill into each one of them.

Dr. Daniels: Right.

Dr. Insel: So we can actually -- because you'd know immediately from the abstract, if not the title --

Dr. Daniels: Right.

Dr. Insel: -- which ones are in kids and which ones are in adults.

Dr. Daniels: Yeah. So you'll -- Dr. Insel is looking at the 2012 portfolio analysis projects list, page 19, objective 4.S.F. And so, you have a full listing of all the projects, and I believe that the electronic versions have live links in them.

Oh, wait. I don't know if these ones have live links. They may not be live because the Web tool is not up for 2012. But you have the titles.

Dr. Farchione: Yeah, you can only do it from 2008 to 2010.

Dr. Daniels: Right. So until the Web tool has been updated, you won't be able to access the abstracts. But in most cases, the titles are fairly informative about what those projects are.

[Pause]

Dr. Batra: So, Susan, this is Anshu. So how do you want us to move forward in terms of identifying, as you mentioned identifying, you know, objectives that perhaps needed more attention, you know, more priority? What else?

Dr. Daniels: So that was pretty much the scope of this call. You have another hour that you could discuss this if you wanted to go through these, and that's why I did send the read-ahead materials so that you would have that opportunity to look through. But even on the call, you could look through some of the lists and get a sense of, you know, whether you wanted to identify a few objectives where you feel that more attention is definitely needed.

It sounds like you may also have other objectives where you feel that not much more attention is needed, that those are well underway.

Dr. Insel: Or I guess if people feel you need more information on any of these, so that question about how many of these involve toddlers, how many school age, how many adults? That information is available. It just takes drilling into the

individual projects to get it and for 2012. But that's -- that's very doable.

So it'd be helpful to know, as we do this first part of the accounting exercise, what you feel you don't have in hand with everything that OARC has put together.

[Pause]

Dr. Batra: Well, this is Anshu. So at least, you know, we have access to the links from 2008 to 2010. We don't have access to the '11 and '12, Susan, which I'm assuming we'll get once you have it on the Web-site.

Dr. Daniels: But that's not going to -- it's not going to be available before October 29th, when you have your workshop. That's probably going to be like November or December or something along those lines.

So you won't have those abstracts. If you need a particular abstract, you can let us know, and we have the information. But we can't bring that up on the Web before that.

Dr. Insel: Susan, on that question, though, so if you just look at this particular one we've got

--

Dr. Daniels: Mm-hmm.

Dr. Insel: -- from in 2009, we had 42 projects. In '10, 30 projects. In '11, 23, and '12, 21 projects.

Dr. Daniels: Mm-hmm.

Dr. Insel: Is it likely that most of the 21 projects in 2012 were -- because these are clinical trials -- were active in 2010? So are projects carrying over?

Dr. Daniels: They do carry over, and so I don't know specifically without looking at it what the --

Dr. Insel: Okay.

Dr. Daniels: -- what the relationship is. You would have to look at those individually, the project lists. But in most cases, I can't even give you a rough estimate of what percentage of projects are carried over from one year to the next, but it's quite a large percentage.

Dr. Insel: Yeah, I mean, if you just think of a timeline for most RCTs as being 4 or 5 years, then you would imagine that most of what was

present in 2010 is still going on in 2012.

Dr. Daniels: Right. And you do have the project title.

Dr. Insel: Right. So that -- but if there's one that can't be tracked in that way, like OARC can check the --

Dr. Daniels: Yes. Yeah, we have all the information in our documents here. They just aren't Web-enabled yet.

But I'm doubting that the group has time to read 5,000 abstracts or whatever we have available. So you probably will want to be selective about anything that you need that's specific. But the titles should be quite informative as to the nature of those activities, though there are some other objectives that are similar to the sixth one down the list here, the next one after that, and one of the last ones also has multiple bullets with different things in it, which, of course, made it challenging in terms of the coding. But in order to break that down, you would have to look at the project list.

But you know I don't know that you necessarily

need to get that far into the weeds to get a sense of are things going well or not going well. It depends on what the Planning Group thinks.

Dr. Insel: Well, I think just looking at this fresh, you know, and following through with the original recommendations, what strikes me the most is the disparity between the number of projects and the dollars. And in the clinical trial space, it makes you wonder whether both public and private funders are supporting lots of underpowered projects, projects that are not going to be able to give a definitive answer because they just don't -- they're not scaled appropriately.

Especially, you know, when I was looking at this complete at least three randomized controlled trials on medications targeting core symptoms in people with ASD of all ages by 2014. And there we've got 14 projects, but the actual total dollars is -- just is under \$4 million, so that means that most of those projects are probably scaled to a very -- to a very small cohort. It makes you wonder whether they will actually be

conclusive.

Dr. Farchione: Yeah, this is Tiffany. I mean, I can say, obviously, without going into any details or specifics, the things that we've seen coming into FDA have been a lot of like small pilot studies, proof-of-concept kinds of things -- very little in the way of anyone attempting any kind of pivotal trial scale.

And even then, you know, that's fraught with complications, too, that I probably can't go into without saying who it was. But it's -- yeah.

Dr. Insel: Yeah.

Dr. Farchione: So, yes, probably -- you're probably right. I mean, with that many studies and that kind of funding, it is because they're, you know, pretty small.

Dr. Insel: So I think this does get to the question that we'll ask next, which is what have we actually gotten out of this? Because what we've seen over and over again is you can launch a lot of exploratory projects, but at the end of the day, you have neither proven nor disproven anything that's of -- that's useful. And it may be

one of the ways, when we come around to commenting on progress, to say it would be better to do fewer things well than a huge number of things in a way that doesn't add up to be informative.

Dr. Daniels: Idil, you -- this is Susan. You mentioned that you were interested in studies of interventions for nonverbal individuals, and there actually is an entire objective devoted to that.

And so, if you were interested in what projects go with that particular topic, you could pull up all the projects, or you could actually just look in the listing that I've provided for 4.S.G and see those projects. And that is one that has received more funding than what was recommended, which again is not saying that it's overfunded necessarily. It just means that it's an area that has a number of projects and is definitely above the floor.

Ms. Abdull: No, I understand. I understand. Thank you. That's kind of -- and I understand what Dr. Insel is saying that these things take time. It's just that it's not -- when you're a parent, you want your kid to get better yesterday, and you

know, a lot of people are just expecting IACC to, including me, just fix the problem. Just tell us what works and we'll be on our way. And it's just autism, even though this is the last 5 years, autism has been here for decades.

And the fact that we can't tell these children or these families which treatment is going to work and has been done through rigorous research and has been proven to be true, I don't know. That just -- it just disappoints me that at this age, you know, in 2013, we can't tell them. Even for ABA, for older kids, it's still not known. It's just for younger children.

So even though behavior gets lots of funding, it's still so much is going for younger children and that -- but the kids get older, and they still have autism. So what do you do with their behaviors?

Dr. Daniels: If you look at page 20 in the -- I guess I'm in the 2011 packet. I don't know what page it is in the 2012. There's a full listing of all the communication intervention studies. So you might be interested in looking through that to see

if you feel that the types of studies that are being covered are -- are addressing the issues that you feel are important.

Ms. Abdull: No, I see that. It's pages 21 and 22.

Dr. Insel: Hmm.

Dr. Daniels: 21 and 22.

Ms. Abdull: I also don't see -- this is Idil again -- for some of the things that Portia mentioned, that even though it's nonverbal, we want them to communicate maybe through machines. But a lot of these children, including my son, could -- are able to read or write, but not speak.

And I think when she was talking about a lot of those therapies are not yet -- they're not funded. They're not even known about it. There is the RPM therapy. I think -- I always forget her name -- but the professor from UCLA was talking about it -- oh, Soma therapy.

And I don't see a lot of ways of teaching children to communicate other than talking, in addition to devices, in addition to augmentative devices. So that's something that I would love to

recommend that we're missing and that we need to -
- we need to utilize how these children
communicate, all the ways that they can
communicate.

Dr. Daniels: In the 2011 listing, I see
something about do animations facilitate symbol
understanding in children with autism --
facilitating speech, digital interactive scene
program. So if you look through the list, there's
a variety, but it still may not cover the issues
that you're concerned about.

Ms. Abdull: No, actually, I've never seen the
RPM or teaching these children the ability to
write. They need someone if they're not able to
say it or not able even to use the machines.

Like the RPM particularly, the RPM, rapid
prompting therapy method that Portia was talking
about. I go to that clinic in Austin, and there
were people all over the world that come from it.
And that method works, yet there is no research
behind it. And, but parents are spending thousands
of dollars out of pocket to get what their
children need that is medically necessary for them

to communicate.

And I just think that -- I really just think that what Anshu said. We need to support what the public wants in addition to what the scientists want. But really what the parents want and what the public wants on the ground, I think we should recommend it in a way that doesn't amend or change the Plan, but in a way that makes it better so that progress is seen on the ground faster.

Dr. Insel: Well, you've just articulated why you're on the IACC. That's your role here,

[Laughter]

And so that -- that needs to be, you know, in the final discussion about the accounting of the Plan in 2013.

Ms. Abdull: I try, Dr. Insel. How's your grandbaby, by the way?

Dr. Insel: Everybody's good.

Ms. Abdull: Good.

Dr. Insel: So what else --

Dr. Daniels: Yes. So on the second page are there any other objectives here that you want to discuss? So that the task for the group is going

to be writing up a summary of what you feel is happening in terms of the funding picture for this question.

Dr. Insel: So say a little bit more about that, Susan. I mean, how do you put or how do you envision this? At the end of the day, when we've done our role, our task here, I get that we have sort of one page describing what's in this table and say of the -- what are there, 12 objectives or something like that? -- that 5 of them look like they have been largely completed and 3 have not and 2, you know, need additional attention, so based on just the investment.

And then another page to say, you know, in 2013, based on the \$309 million that has been spent on Question 4, this is what we know about which treatments and interventions will help. So there's like -- there's like a two-page progress report on each question. Is that how you --

Dr. Daniels: That's approximately, I think, what the Question 1 Planning Group had come up with, and that's the -- for those who are listening on the phone that might not know all

that background, a small group got together. It was -- they worked with pilot data from Question 1 to come up with a process for doing this -- this accountability review over the past 5 years.

And so it was determined that it would be good to look at things from the funding perspective using the data that OARC has collected over the past 5 years and then to do more of a qualitative look at what the results and outcomes have been and where the -- where all of this tells us we need to go. And so we broke down the process in this guidance sheet that was provided to you just to make it a little easier for you, having you look at the funding information in the first meeting and then coming up with a summary.

We gave a guideline of three to five pages. It could be much shorter if you'd prefer it to be shorter. It doesn't have to be that long, but we wanted to give you enough room to say whatever it is that the Planning Group feels needs to be said about this. To give a reader a sense of what really has been the progress in terms of are we investing appropriately in the areas that the IACC

has recommended as priorities?

And if there are deficiencies, what are those deficiencies? Just to highlight them so that it can be prioritized for further attention.

Dr. Insel: Okay. So what the first page -- in terms of what we're doing today, the summary can say something like of these objectives -- actually, as I look through it, I think in every one of them, we have either met or exceeded the number of projects that were called for in the original Plan. But the dollars have fallen short in many cases, suggesting that there may be projects that are -- that are smaller rather than the original vision of having large-scale RCTs. But what more could we say about this?

Dr. Daniels: You also could identify barriers. For example, with the 10th objective in this list, 4.L.B, which is on the second page of the cumulative funding table: "Develop interventions for siblings of people with ASD with a goal of reducing the risk of recurrence by 30 percent by 2014." Just based on my look at this, in 2012, we have two projects and definitely not very close to

the IACC-recommended budget. I would imagine --

Dr. Insel: I'm sorry. Where are you looking?
What is that?

Dr. Daniels: I'm looking at this one.

Dr. Insel: Oh, the third one on the second
page.

Dr. Daniels: 4.L.B. So does the Planning Group
have any sense of why we might not be able to do
that, or what's the barrier that's preventing that
from moving forward further? The two projects
should be fairly easy to look up in the funding
tables that we -- or the project listing, sorry,
that we provided. So I have a --

[Inaudible comment]

Dr. Batra: Excuse me. This is Anshu. I don't
think we were provided the table for 2011 and
2012. Correct?

Dr. Daniels: I thought you were. Yes, I know I
attached them to the emails, or I think I attached
them to the email.

Dr. Farchione: Yeah, they're in there. They're
just not hyperlinked.

Dr. Insel: Right.

Dr. Farchione: Yeah, they're not hyperlinked.

Dr. Daniels: So it's not hyperlinked from the table, but you have an actual listing. It's a large document. It's a big PDF with something like 30 pages apiece, 34 pages on the 2011. And we've actually given you all the text -- so list of the project titles, the investigator, the institution, the funding, and the funders for those.

And so on page 24 of the 2011 packet, the two projects that are funded -- one is funded by the Center for Autism and Related Disorders and one is from the Simons Foundation -- preventing autism via very early detection and intervention and executive functioning, theory of mind, and neurodevelopmental outcomes are the two projects.

And so it looks like there hasn't been much activity in this area, and I don't know if the Planning Group might have a sense of why. Is there something in that objective that might be a barrier? And it might not be something the Planning Group can determine based on just the funding information. You might really need the experts to comment on this to give a sense of why

there isn't more activity.

Dr. Batra: Susan, this is Anshu. You know, looking at this, I think one of the problems is that, you know, we -- you know -- you know, we're still identifying these, you know, kids through, you know, symptoms of, you know, whether it's the language or behavior. And again, I think that very often, you know, these kids present with earlier -- at least in my experience and in my practice -- with, you know, the verbal and the behavioral symptoms are really -- you know, they're latecomers in development.

And I think that, you know, we're just not looking at some of the earlier, you know, sensory and motor issues that these kids have that then later on develop verbal and behavioral challenges that we see in autism. So it may be that we're just not targeting, you know, the right features. And looking at the three projects, they really are -- you know -- they're looking at behaviors.

Dr. Daniels: Right.

Dr. Insel: Anshu, I think that's a great point. I mean, I think just as someone who thinks

about how to stage the science, I would imagine that you'd want to do a better job of being able to detect risk before developing an intervention.

So I just wonder whether this was ever really thought through that carefully.

The current recurrence risk, as far as we know is about 20 percent. So to develop an intervention for sibs that would reduce that by 30 percent, you'd want to begin by knowing which sibs do you really need to be concerned about, and we don't yet have a biomarker to predict this. That's actually back in Question 2 or 3.

Dr. Batra: Well, that's actually Question 1, Tom.

Dr. Insel: Question 1, okay.

Dr. Batra: And we have the third in Question 1 that was exactly the point I brought up -- was that, you know, the things that we -- in Question 1, the objectives that were laid out really were not looking at those really early, early features. And you know -- and either developing tools or testing existing developmental tools to assess risk factors for ongoing, you know, development of

autism. And you know?

Dr. Insel: Right.

Dr. Batra: And so and again, I can't remember the numbers, but it was significantly, you know, much more funding that was -- that was used for developing, you know, a new autism tool, which in my mind as a pediatrician, you know, I don't need an autism tool. You know, I look at development early on, and what goes awry in development that then goes on to then develop the features of autism.

And again, you know, we -- as pediatricians, we look at early motor. We look at the motor system first, and then -- because that's the foundation of how the brain links itself and very often those are the kiddos that you very often will -- will then go on and be at risk for ongoing delays in neurodevelopment, whether it's autism or another related disorder. So --

Dr. Insel: And that's just -- just looking at the list from 2012, so one of the two projects is -- looks like it's going exactly in that direction. The title is "Targeting Joint

Engagement in Infants at Risk for ASD: Integrating Treatment with Biomarkers.”

So the hope is to, whether it's through looking at sensory motor development or whatever else might be there, figuring out which kid is going to need to have the intervention. And one would hope, since, you know, it's only about one in five who are going to develop autism that you would be able to focus this down a little bit better so you'd know who to work with.

So I guess my sense of this, to get back to Susan's question, is that it doesn't give me a lot of heartburn that this is a project that's in the yellow zone. It's a really ambitious thing to develop interventions for kids at risk until you know how to find the kids at risk much better than we can now.

So I would actually worry if we were spending a huge amount here because I don't think it would be money invested wisely yet until we do what was in Question 1 and a little bit in 2 and 3, which is to get a deeper understanding of the trajectory before symptoms develop.

That, and once you have that then you're ready to think about what the intervention should be.

Dr. Batra: Right. Tom, I would wholeheartedly agree with you on that. And you know, in looking at one, two, three, four, five -- the fifth one on that second page, supporting at least five community-based studies, now clearly, you know, the number of studies it looks like is in the green zone. But if you look at the specific projects, you know, there is again disparity in terms of what they're looking at, and the objective is really very -- you know, it's very broad in terms of looking at, you know, medical, pharmacological, nutritional, behavioral, you know, parent giving treatment plans.

And so I think sifting through -- I think that's a very difficult -- I think it shows that it's been, you know, it's been funded and there's been, you know, it's in the yellow zone. But if you really look at it specifically, I think there's a disparity within that.

And personally, as a parent and as a pediatrician, this specifically for me would be

very important, seeing what tools, what interventions are -- have been -- shown to be effective in the community, as opposed to, you know, were there large randomized controlled studies that are expensive and can be very costly.

So I would -- yeah, I would like to know what other -- what specific projects have been -- I guess I have to look at -- I didn't realize that we had that document. I'm sorry about that, Susan.

Dr. Daniels: Right. We have that. So if you're in the 2011 document, it's page 25, and it must be something similar in the 2012.

So there are a large number of studies, and they're pretty broadly covering a lot of different agencies. Some of them are, you know, the Department of Education has a number that are educational-type interventions, and other agencies have other health-related interventions.

Dr. Insel: Yeah, I had exactly that same response. In looking at this list and reading through it, a lot of them have zero dollars. Is that because they're --

Dr. Daniels: What is zero dollars? You mean --

Dr. Insel: -- they have zero dollars listed with the project.

Dr. Daniels: Oh. Oh, that means that it's probably an out-year. Some agencies do lump-sum funding on the first year.

Dr. Insel: Oh, so it's still underway, but the money all came in the first year? Okay.

Dr. Daniels: First year, mm-hmm.

Dr. Insel: But, you know, what is striking is the number of these that look relatively small, and it's like 1,000 flowers are blooming here. And you wonder if any of these have been set up rigorously enough to be able to disprove the intervention, be able to show that the intervention is not effective.

Because that is a real concern, and you wonder also whether any of them have been developed in a way that you could understand the mechanism by which they work so that if you do get an effect, you'd know what to build upon. So --

Dr. Batra: Tom, this is Anshu. I think that that would be very difficult to -- to -- to tease out what works and what doesn't work until, you

know, until we really start identifying, you know, the -- the sort of subtypes within autism.

Because, you know, clearly, at least in my experience, you know, there are different phenotypes of children on the spectrum, and they respond to different treatments.

So for us to say that one treatment is -- is, you know, is disproved, you know, I think that would be throwing the baby out with the bathwater, you know? And so, yeah, I think that would be -- that would be -- I don't think that would be as concerning to me as, you know, looking at these, at this list.

You know, I don't think it really covers the scope of what's -- what's out there in the community.

Dr. Insel: You mean the scope of interventions?

Dr. Batra: Yeah, the scope of interventions. You know, I look at this, and I think -- I don't think -- I don't recommend it most of these interventions, and I haven't used most of these interventions for my own child, you know? I would

like to see more of what's actually being -- being used in the community.

Dr. Daniels: Anshu, are you looking at the listing as you're describing this?

Dr. Batra: I'm looking at 28, page 28.

Dr. Daniels: Okay.

Dr. Insel: Mm-hmm.

Dr. Daniels: Yeah.

Dr. Batra: I'm looking at things like, you know -- I think, again, some of these are very appropriate, and I can see them being very relevant to -- to the families. But to be honest, I mean, you know, the things that patients who come to me and ask me, "Should I -- should I do this, Dr. Batra," you know? "What else can I do for my child?" We're not looking at those things.

Dr. Insel: So I think that's just exactly where -- what this task is all about, what you just said. I mean, I think, so we're at the point where we can say, hey, there's a lot of money, a lot of projects, a lot of people involved. So that's the investment. And then we have to ask, what's the return?

And what you're just telling us is that you look through this list, and none of this looks like it's at this point answering the critical questions that you, as a provider or as a parent, would have. Is that fair to say?

Dr. Batra: Absolutely.

Ms. Abdull: Can I also add -- this is Idil. I agree with what you're saying, Dr. Insel, in that it just seems like there are 1,000 flowers, and so -- and there's not enough money -- and so, if you spend, you know, \$30,000 or \$10,000, some of them have, I suppose if you did enough money and did one good study and found out, either disproved or proved how that one works. So then we have a good thing to go on, as opposed to having -- it's like going to school and studying 10 subjects but never really knowing enough to pass any of them.

So I would prefer if we had -- if we used, you know, our bucks for the most bang. Do enough of the ones that we're using on the ground, in addition to what the scientists -- I'm thinking a lot of these are what the researchers wanted to do, in addition to what's recommended -- but do it

in a way that either proves or disproves that therapy so that we're not asking years and years and years does it really work? Do we know it's a controlled trial? Has it been proven or disproven?

It just seems there are a lot of flowers and not enough proof, you know? Just not enough to take it to the floor and to the ground.

Dr. Batra: Yeah, and not enough -- not enough information for me then to be really -- to really be able definitively give that information to my patients, you know?

And I'll be very honest. Like, I mean, that is what we parents, that is what my patients want. We want to know, you know, what can help my child? Should I do this? Should I not do this?

And I frankly -- I'll be honest. Every single day what I say is, well, I'm not sure exactly what would be the best thing, but in my experience and in other people's observational experience, this is what -- let's try this. And I'm putting my medical license on the line every single day because of that.

But that's all I can do because I don't have

anything else to provide them, other than my experience and other people's experience and -- and due diligence just with that.

Ms. Abdull: And if I can just add, as a mom, autism therapy really is -- it's a seller's market. As an autism mom, you can sell me poop as a treatment, and I would probably try it. It's just we need -- we need therapy that works. We need to know that as parents so that it's not a seller's market, so that parents are educated and that's because they know it's been done. Research has been done. It has been either proven or disproven.

Anybody can sell you now. Anybody can say, "This is the treatment. I know because I've seen 10 other people." But you want to do what NIH and CDC and FDA, what they've proven, but there is just not enough. There is not enough on the ground for us as moms and dads, and I think we just need to condense it in a way that makes sense at the end of the day which treatment works. Here -- here they are.

Dr. Batra: Yeah, and Idil -- just to piggyback

and look at treatments that are relevant to what people are actually doing as opposed to what scientists think should be done. And you know, I guess that is the biggest frustration for me is that I looked -- you know, I look at this whole list, and I think nothing here is relevant to me, nothing. And that's so disappointing and frustrating.

Dr. Insel: So I wonder if this conversation, which is really important for our process, ought to be continued with at the next call when we bring the experts in, because the question we're going to have to put to this group, including these external experts, is relative to where we were in 2008, what do we know about interventions now that we didn't know then. And what's underway that will answer the questions that you're bringing up.

And it sounds like from the standpoint of the people who are on this call, you have real concerns about the lack of progress and the number of things we don't know. But I think it will be good to bring in others as well who can weigh in

on this.

So I don't want to come to any closure on this question until we have the second call, which was scheduled precisely to -- to look at what has been the return on the investment. So the only thing we really have to do today, if I understand this right, Susan, is come to some conclusion about looking at the dollars and the number of grants, where we sit in 2013.

And going back over the 5 years and the 12 objectives, have we -- which ones have we fulfilled in terms of the original projections and which ones require more attention? And I'm hearing that there are some places where people feel there hasn't been enough work or there hasn't been maybe deep enough work in some areas, and then other areas that have been heavily invested in already.

And I think, you know, what you've done, you've actually done most of the work for us by getting us all the green, yellow, and red highlights. But is there more that we would need to do today beyond just that accounting?

Dr. Daniels: Really, I think that you captured

it. We were hoping that you would on this call get a sense for the portfolio and the health of this portfolio. Is it moving in the right direction on all of these different objectives? The intent of the Committee to stimulate more research in some of these areas, is that happening adequately? Are there -- are there ones where things aren't happening as well as you would like?

I think on 4.L.B, you identified a possible scientific barrier to achieving that particular objective. Some of the others that have few projects -- for example, the health promotion and prevention one -- some of the others that don't seem to have as much activity, if there are any hypotheses you have about what might be preventing those from moving forward, that would be helpful.

And then, at the end of this call, we can decide who might be able to write up a brief summary, and it doesn't have to be a long summary. We did give you latitude to have something up to five pages, but it could just be a page that gives a sense for this Planning Group's thoughts about this area and what we can learn from the funding

picture.

And don't feel like you have to really deeply look into all the funding issues because OARC will be putting out a report in the next couple of months that will cover all the funding for 2011 and 2012 in terms of deeper analysis.

Dr. Batra: Susan, this is Anshu. One other comment I wanted to make. You asked about other objectives. And if you look at 4.S.1, there are really only three studies that have been published for comorbidities, and specifically, looking at them, you know, one is anxiety. One is, you know, epilepsy, and you know, these -- there are so many more, many more comorbidities that we see in children with autism, individuals with autism that are not being looked at.

So, again, it's a comment. I don't know why. I don't think we can answer that question specifically, but that's another observation here.

Dr. Daniels: That's 4.L.C you're talking about?

Dr. Batra: 4.S.A.

Dr. Daniels: 4.S.A.

Dr. Insel: What page is that on the listing?

Dr. Batra: Two. Number 2, page 2.

Dr. Daniels: Oh, okay.

Dr. Insel: Oh.

Dr. Batra: And you know, I think that listening to parents at the meetings or others at the meetings, I think the comorbidity issue is -- is a huge one. And you know, I know my son has -- has several of the comorbidities. I know my patients do, and we have three projects that are funded.

Dr. Daniels: Right. There are also projects just -- this is Susan from OARC -- knowing the portfolio, through the portfolio analysis, there are a lot of projects funded that are still in the basic science area trying to understand the comorbidities. And so this is the section that would be talking about specific treatments, and you are correct that there are three projects that we've identified for 2012. So other thoughts about that?

Dr. Batra: This is Anshu. [Inaudible comment]
We're not looking at it enough, and we're not

looking at it broadly enough.

Ms. Abdull: Hi, this is Idil. Dr. Daniels, don't we have like a -- is it a subcommittee for comorbidities or --

Dr. Daniels: So there is a plan - there will be a planning group --

Ms. Abdull: I agree with Anshu --

Dr. Daniels: -- there will be a planning group for the comorbidity --

Ms. Abdull: Right. Which is what I think everybody -- and I agree with you, Anshu, that said, there is just not enough that we know or that we've done for comorbidities. So it's a good idea to see what that planning group comes up with and how to address that, because they do exist.

So many of these children have lots of problems, not just autism. They have other issues, other medical issues.

[Pause]

Dr. Daniels: So in the listing that you have - - or I guess in the 2011 listing that I have -- we've got a sleep study, a GI study, and then AIR-P from HRSA, the Autism Intervention Research

Network, which is a huge project, \$1.7 million. So I'm not sure -- that's Dr. Perrin's study. So I'm not sure what all is in there, but he may be in that study addressing a number of comorbidities. But you'd have to look at the abstract to see what all is in there.

Dr. Insel: But again, I think this is a good balance question. Given how much we've heard in the deliberations of the Committee about this, kind of striking how little is being done in this area, and it was in the Plan. So it will be interesting, though.

I mean, it essentially said conduct at least one study to evaluate the safety and effectiveness. So the Committee itself was, at least in 2008, pretty modest in what its expectations were. So that may be one of the places that we'd want to comment on in 2013.

So in terms of putting a quick text summary together, I'm willing to take a swing at this very quickly and just give a very kind of rough skeleton or rough draft that I could circulate to other people in the Group and then go from there,

and we just try to turn this around in a couple of days.

Dr. Daniels: That would be terrific.

Dr. Insel: Okay.

Dr. Daniels: And then we could pass it around the Planning Group, and you can all put in your comments and --

Dr. Insel: It would help me a little bit in doing that if you could look at the -- the one that's in red. I'm still suspicious that that should be --

Dr. Daniels: Yes. We can -- we'll look into that. We'll get that information.

Dr. Insel: So if you could -- if we can get that done. And then I think given the other comments that people have made here, I think we have -- I think the two big issues I'm taking away from this conversation are concerns about the overall balance of how the investments are being made with respect to the 12 objectives, especially around number 3 here, the five widely used interventions getting that seems to be underinvested.

And then the second issue is the number of projects relative to the number of dollars seems to suggest that there's lots going on that maybe is really underpowered to be able to be definitive. And while that sometimes happens at an early stage in a research area, one would have hoped that over 5 years we'd have gotten to a point where people are ready to do larger scale efficacy and effectiveness trials, and I don't see that as I look through the list of projects. It's really kind of stunning how many tiny exploratory projects are in there.

And what we've often found at NIH is that you can do those for a long time and not really walk away with anything besides a manuscript, and we ought to be able to do better than that.

So that would be the -- the tone of my comments. But I'll send them to you, other members of the Committee, and then if you can -- we can just do this electronically. When is the second call?

Dr. Daniels: The second call is going to be scheduled. It's not been scheduled yet. So we will

be getting in touch with you all to get a time. And luckily, this is a small Group. So we hope that we'll be able to facilitate getting that call scheduled soon.

Dr. Insel: Because I think that that's going to be really important in how we describe this. I think the really critical question here is having spent whatever that number was, some huge dollar amount of \$309 million, what have we gotten? What do we know now that we didn't know before?

And it's fine to say that this is all in process and we'll know much more in a couple of years when some of these projects finish. But, frankly, looking at the list of projects, I think that's true in some areas but maybe not so much in others. So this is really helpful to have it all laid out this way.

Dr. Daniels: Great. Well, thanks. I'm glad that you found all the information helpful.

Is there anything else that the Committee wants us to follow up on in OARC? We will be drafting some minutes and circulate those, just as a reminder of what we've discussed on today's

call. And then Dr. Insel graciously volunteered to put together a first draft of a summary for this Group.

Dr. Insel: It will be rough, a very rough draft, just for something, something for people to work from.

Dr. Daniels: Everyone is welcome to -- to put information together for that.

And for anyone who's listening in on this call, we will be having a meeting of the full IACC on October 9th and then a meeting for updating the Strategic Plan, which will be a workshop with the full Committee as well as our external experts, and that will be taking place on October 29th. And we will be sending out email announcements and putting up more information on our Web site as it develops to keep you informed of those upcoming events.

Dr. Batra: Tom, this is Anshu.

Dr. Insel: Yeah?

Dr. Batra: Can I make a comment?

Dr. Insel: Sure. Go ahead.

Dr. Batra: I'm sorry. First of all, thank you

for putting together that summary. I think that that's going to be very helpful for us all.

Secondly, I'm curious, you know -- Susan was mentioning at the second call we will have our subsequent list and the community experts to help us with some of these questions we've been posing today. And my question is, in terms of the community experts, you know, the people that are - - you know, who've been applying a lot of these interventions that maybe don't have as much -- as of the research base behind them, how are you selecting those community experts?

Because, you know, in my experience, very often community experts are not ones that are nationally renowned, as in the research arena, and so, you know, how -- you know, how will they be chosen to then help us answer some of these questions about these interventions that we're asking in terms of, you know, how efficacious are they and where are we now with the use of these interventions in the community?

Dr. Daniels: So, Anshu, I have sent out an email to the full Committee explaining a little

bit about this, and I will be sending out further emails about setting up things for the October 29th workshop and the rest of this process.

All of the IACC Committee members were given the opportunity to provide nominations of people to serve as external invited participants in this planning process. Those names have been given to the Subcommittee chairs, and the Subcommittee chairs are working with us in OARC to try to get together a group of external participants who can help us with each of the question areas. But more information will be shared by email.

Dr. Batra: Thanks.

Dr. Insel: Any other questions, comments, thoughts?

Dr. Insel: Okay. Susan?

Dr. Daniels: Well, thank you, everyone. If there are no additional questions, as I said, we'll be in touch by email as things develop. We're keeping quite busy in OARC trying to get all of these meetings organized and arranged and to put together all the preparations, and so we'll be keeping you informed of these developments.

And we appreciate your effort looking at all of this and really putting your minds into thinking about how this -- how the progress -- is going in these areas and how we can improve the Plan and efforts that are being coordinated across Federal and private sectors.

So thanks so much for joining us, and we will be in touch soon.

Dr. Farchione: Thanks, Susan.

Dr. Batra: Good-bye. Thank you.

Dr. Daniels: Thanks, everyone. Bye-bye.

Operator: And this concludes today's conference. Thank you for participating. You may disconnect at this time.

Dr. Daniels: Thank you.

(Whereupon, the conference call of the Strategic Plan Question 4 Planning Group was adjourned.)